

REMARKS

Preliminary Remarks

Reconsideration and allowance of the present application based on the following remarks are respectfully requested. Upon incorporation of the amendment of September 13, 2004, and the present amendment, claims 1, 2, 6, 7, and 28-30 are currently pending in this application and remain at issue.

The applicants do not intend by these or any amendments to abandon subject matter of the claims as originally filed or later presented, and reserve the right to pursue such subject matter in continuing applications.

RCE

By the enclosure, the applicants have requested entry of this amendment and response and have further requested removal of the finality of the outstanding official action.

Additional Fee

Although the applicants believe additional fees (beyond those presented herein) are not necessary for entry and consideration of this amendment/response, should the USPTO determine additional fees are due (for such consideration), the Patent Office is authorized to charge such fees to USPTO Deposit Account No. 03-3975.

Patentability Remarks

Rejection Under 35 U.S.C. §112, Second Paragraph

In paragraphs 3 and 4 of the advisory action, the examiner rejected amended claim 7 and proposed new claim 28 under 35 U.S.C. §112, second paragraph, for being indefinite. Specifically, the examiner alleged that the recitation "the process according to claim 1 wherein one or more *E. coli* genes(*i.e.*, *tdh*, *mdh*, *yifA*, *ytfP*) are inactivated by one or more methods of mutagenesis (*i.e.*, deletion, insertional mutagenesis due to homologous recombination, and transition or traversal mutagenesis with the incorporation of a non-sense mutation) during fermentation for the preparation of said L-amino acids" is unclear as to how one can inactivate a gene using mutagenesis during a fermentation stage. With regard to new claim 28, the examiner asserted that the phrase "the process of claim 1, wherein the

constituents of the fermentation broth and the biomass in its entirety or portions thereof being isolated as a solid product" is unclear.

Amended claim 7 is now directed to the process according to claim 1, wherein one or more *E. coli* genes selected from the group consisting of (a) the *ldh* gene coding for threonine dehydrogenase, (b) the *mdh* gene coding for malate dehydrogenase, (c) the gene product of the open reading frame (orf) *yifA*, and (d) the gene product of the open reading frame (orf) *yifP*, are inactivated by one or more methods of mutagenesis selected from the group consisting of deletion, insertional mutagenesis due to homologous recombination, and transition or traversal mutagenesis with incorporation of a non-sense mutation in the *pckA* gene. The applicants respectfully submit that claim 7 is no longer unclear as to the time frame (*i.e.*, during the fermentation stage) of when a particular gene is inactivate using the mutagenesis methods recited.

Amended claim 28 is now directed to the process of claim 1, wherein constituents of the fermentation broth and the biomass in its entirety or portions thereof are isolated as a solid product together with said L-amino acids. The applicants submit amended claim 28 is now clear based upon the examiner's suggestion for which the applicants are grateful. Accordingly, in view of the foregoing amendment and remarks, the applicants submit that the rejection of claims 7 and 28 under 35 U.S.C. §112, second paragraph, has been overcome and should be withdrawn.

Rejection Under 35 U.S.C. §112, First Paragraph

In paragraph 5 of the advisory action, the examiner rejected new claims 29 and 30 under 35 U.S.C §112, first paragraph, as failing to comply with the enablement requirement. Specifically, the examiner alleged that the claimed process use specific *E. coli* strains DSM 13761 (*E. coli* strain MG442Δ*pckA*) and DSM 14150 (*E. coli* strain B3396kurΔ*tdh*Δ*pckA*/pVIC40), but there is no indication in the specification as to the public availability of these strains.

The applicants submit herewith a declaration by the undersigned stating that *E. coli* strain MG442Δ*pckA* has been deposited under the Budapest Treaty as DSM Accession No. 13761, deposited on October 2, 2000 at the Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH (DSMZ) Mascheroder Weg 1B, D-3300 Braunschweig, Germany (DSMZ = German Collection of Microorganisms and Cell Cultures, Braunschweig, Germany). In

addition, the applicants submit that the declaration further states that *E. coli* strain B3396kur Δ tdh Δ pckA/pVIC40 has been deposited under the Budapest Treaty as DSM 14150 on March 9th, 2001 at the same depository. In view of the foregoing submission and remarks, the applicants submit that the rejection of claims 29 and 30 under 35 U.S.C. §112, first paragraph, for lacking an enabling deposit has been overcome and should be withdrawn.

Rejection Under Nonstatutory Double Patenting

In paragraphs 6 and 7 of the advisory action, the examiner provisionally rejected amended claim 1 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 35 of co-pending U.S. Patent Appl. No. 10/114073, claims 46-50 of co-pending U.S. Patent Appl. No. 10/114043, claims 12-14 of co-pending U.S. Patent Appl. No. 10/114048, and claim 31 of co-pending U.S. Patent Appl. No. 10/076416. The examiner asserted that claim 35 of co-pending U.S. Patent Appl. No. 10/114073 and claim 31 of co-pending U.S. Patent Appl. No. 10/076416 refer to the reduction or elimination of expression of the pckA gene, and therefore anticipate the inactivation of the pckA gene as directed in claim 1. The examiner further alleged that the disclosure of co-pending U.S. Patent Appl. Nos. 10/114073, 10/076416, and 10/114043 describe attenuation as reduction or switching off of the intracellular activity of an enzyme by inactivation of the gene such as by transitions, traversions, insertions and deletions. The examiner concluded that amended claim 1 would be considered obvious over the above-identified applications.

The applicants respectfully traverse the examiner's assertion that U.S. Patent Appl. Nos. 10/076416, 10/114073, 10/114048, and 10/114043 anticipate the inactivation of the pckA gene, and accordingly make amended claim 1 obvious over the above-identified applications. The applicants further submit that the examiner is using a nonstatutory double patenting which is not the usual "obviousness-type" double patenting rejection and is rare and limited to the particular factors of the case. The examiner can continue to make "provisional" double patent rejections in each application as long as there are conflicting claims in more than one application unless that "provisional" double patent rejection is the only rejection remaining in one of the applications. If the "provisional" double patenting rejection in one application is the only rejection remaining in that application, the examiner should then withdraw that rejection and permit the application to issue as a patent, thereby converting the "provisional" double patenting rejection in the other application(s) into a double patenting rejection at the time the one application issues as a patent. See MPEP §804 (I)(B) The


applicants submit their application has the earliest filing date. The applicants submit the present non-statutory double patenting rejection for the above-identified application should be withdrawn because the applicants believe (1) the "provisional" double patent rejection is the only rejection remaining in the application, and (2) the above-identified application has an earlier filing date than co-pending U.S. patent applications co-pending U.S. Patent Appl. Nos. 10/114073, 10/076416, and 10/11043. Accordingly, the applicants respectfully submit that the provisional rejection of claim 1 under the statutory created doctrine of obviousness should be withdrawn based on the fact that this rejection is the last remaining issue in the present application.

CONCLUSION

In view of the foregoing, the claims are now believed to be in form for allowance, and such action such action is hereby solicited. If any point remains in issue which the examiner feels may be best resolved through a personal or telephone interview, please contact the undersigned at the telephone number listed below.

Respectfully submitted,

PILLSBURY WINTHROP LLP

By: 
THOMAS A. CAWLEY, JR., Ph.D.
Reg. No. 40944
Tel. No. (703) 905-2144
Fax No. (703) 905-2500

TAC/PAJ/wks
P.O. Box 10500
McLean, VA 22102
(703) 905-2000